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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,883	12/21/2001	Toshio Miyata	SHIM012	2901

24353 7590 01/05/2004

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/05/2004

18

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/936,883

**Applicant(s)**

MIYATA, TOSHIO

**Examiner**

Gary W. Counts

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) g.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the claims***

The election and amendment filed October 23, 2003 is acknowledged and has been entered. Applicant's amendment to the claims and remarks concerning the election restriction has been considered and therefore claims 1-18 have been examined.

### ***Specification***

The disclosure is objected to because of the following informalities: On page 1, line 23 of the specification. The disclosure " Y 6 million" should be --6 million--.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3, 5, 10 and 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the preamble of the claim does not correlate with the body of the claim. The preamble of the claim recites a method for evaluating renal functions. However, the body of the claim does not positively recite evaluating renal functions.

Claim 1 is vague and indefinite because it is unclear how determining the amount of megsin protein correlates to renal function. Does an increase or decrease in the

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amount of megsin protein indicate renal function? Furthermore, how does one determine if the amount of megsin protein in a biological sample is increased or decreased? Is the amount of megsin protein detected in the biological sample compared to a standard or control?

Claim 2, line 3 the recitation "normal specimen" is vague and indefinite. The term "normal" is a relative term which renders the claim indefinite. It is unclear what is considered to be normal.

Claim 10 is vague and indefinite because it is unclear what applicant intends.

Claim 12 is vague and indefinite because it is unclear what relationship exists between the granule and the marker molecule. Does the granule bind to the marker molecule? Or does the antibody on the granule bind to the analyte and the marker molecule also bind to the analyte?

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 6 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsujimoto et al., (Purification, cDNA Cloning and Characterization of a New Serpin with Megakaryocyte Maturation Activity, Journal of Biological Chemistry, Vol 272, No. 24, June 1997).

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Tusujimoto et al disclose a protein comprised of amino acid sequence consisting of 380 residues. Tusujimoto et al disclose monoclonal antibodies directed to the protein which are used to detect the protein (p. 15377).

With respect to the megsin protein as recited in the instant claims. Even though Tusujimoto et al does not explicitly state that the protein is megsin, it is inherent that the amino acid residue constitute the megsin protein. Therefore, since Tusujimoto et al disclose monoclonal antibodies directed to this protein, Tusujimoto et al anticipates the instantly recited claims.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 2, 5-9, 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombinski (US 6,297,062) in view of Tsujimoto et al., (Purification,

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cDNA Cloning and Characterization of a New Serpin with Megakaryocyte Maturation Activity, Journal of Biological Chemistry, Vol 272, No. 24, June 1997).

Gombinski disclose methods for detecting and determining biological entities in a test sample. Gombinski disclose magnetic particles which may have antibodies immobilized on the surface of the particles. Gombinski disclose that these magnetic particles containing the immobilized antibody will bind to the biological entity.

Gombinski disclose that this biological entity can be a protein (col 3 and 4). Gombinski disclose that the magnetic particle containing the immobilized antibody and the biological entity and be further subjected to monoclonal antibodies linked to detectable markers (marker molecule) to detect the biological entity (col 12, lines 49-67).

Gombinski disclose the use of a magnet with the magnetic particles. Gombinski disclose kits for carrying out the methods (col 10 and abstract). Gombinski disclose that the sample can be any type of liquid media which may contain the biological entity to be detected.

Gombinski differ from the instant invention in failing to teach the antibodies are anti-megsin antibodies.

Tusujimoto et al disclose a protein comprised of amino acid sequence consisting of 380 residues. Tusujimoto et al disclose monoclonal antibodies designated 35 and 336 directed to the protein which are used to detect the protein (p. 15377).

It would have been obvious to one of ordinary skill in the art to use the antibodies taught by Tusujimoto et al in the method and kit of Gombinski because Gombinski is generic with respect to the biological entity (analyte) that is to be detected and one

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would use the appropriate reagent, i.e. antibody to detect the desired analyte, in this case megsin protein.

8. Claims 1-3, 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohr (US 5,445,970) in view of Tsujimoto et al., (Purification, cDNA Cloning and Characterization of a New Serpin with Megakaryocyte Maturation Activity, Journal of Biological Chemistry, Vol 272, No. 24, June 1997).

Rohr disclose magnetic particles (granules) having binding members immobilized on the surface (col 6, lines 36-62). Rohr disclose that these binding members can be antibodies (col 5). Rohr disclose that these magnetic particles are used to determine the presence or amount of analyte in a test fluid. Rohr disclose that this test fluid can be urine (col 4, lines 59-68). Rohr disclose that these magnetic particles can be used to determine any analyte of interest for which there exists a naturally occurring binding member or for which a binding member can be prepared.

Rohr differs from the instant invention in failing to specifically teach that the antibody is anti-megsin antibody.

Tsujimoto et al disclose a protein comprised of amino acid sequence consisting of 380 residues. Tsujimoto et al disclose monoclonal antibodies directed to the protein which are used to detect the protein (p. 15377).

It would have been obvious to one of ordinary skill in the art to use the antibodies taught by Tsujimoto et al in the method of Rohr because Rohr specifically teaches that magnetic particles can be used to determine any analyte of interest for which there exists a naturally occurring binding member or for which a binding member can be

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prepared and thus, one would use the appropriate reagent, i.e. antibody to detect the desired analyte, in this case megsin protein.

With respect to the megsin protein as recited in the instant claims. Even though Tusujimoto et al does not explicitly state that the protein is megsin, it is inherent that the amino acid residue constitute the megsin protein. Therefore, since Tusujimoto et al disclose monoclonal antibodies directed to this protein, Tusujimoto et al anticipates the instantly recited claims.

### ***Conclusion***

Miyata et al (A mesangium-predominant Gene, Megsin, Is a New Serpin Upregulated in IgA Nephropathy, J. Clin. Invest. 120(4): 828-836 (1998). Miyata et al disclose studies that showed the megsin expression in the mesangium of normal glomeruli, were increased in the expanded mesangium of glomeruli from patients with IgA nephropathy.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary Counts  
Examiner  
Art Unit 1641  
December 22, 2003



LOUIE  
SUPERVISOR, EXAMINER  
TECHNOLOGY CENTER

12/24/03